IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (JLH) [redacted] **PUBLIC VERSION**
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	**Confidential Version Filed: January 26, 2024** **Public Version Filed: February 2, 2024**

SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S REPLY IN SUPPORT OF THEIR MOTIONS FOR SUMMARY JUDGMENT

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TABLE OF ABBREVIATIONS

Abbreviation	Description
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'092 Patent	U.S. Patent No. 10,385,092
'461 Patent	U.S. Patent No. 10,407,461
'106 Patent	U.S. Patent No. 10,487,106
'741 Patent	U.S. Patent No. 10,647,741
'217 Patent	U.S. Patent No. 10,662,217
'322 Patent	U.S. Patent No. 10,683,322
ASO	Antisense oligonucleotide
Bold and Italic	Emphasis added unless indicated otherwise
Ex. ____	Exhibit ____[1]
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Japan	Plaintiff/Counter-Defendant Nippon Shinyaku Co., Ltd.
NS Pharma	Counter-Defendant NS Pharma, Inc.
NS Patents	U.S. Patent Nos. 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; 10,683,322
PTO	United States Patent and Trademark Office
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
UWA	Counter-Plaintiff The University of Western Australia
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827
Wilton Product Patents	U.S. Patent Nos. 9,994,851; 10,227,590

[1] Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Replies to Their Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Plaintiff/Counter-Defendants' Experts.

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I. INTRODUCTION

Sarepta and UWA respectfully request that the Court grant summary judgment that:

(1) NS infringes claims 1 and 2 of U.S. Patent No. 9,994,851 and claims 1 and 2 of U.S. Patent No. 10,227,590;

(2) Nippon Shinyaku Co., Ltd. ("NS Japan") is not entitled to recover lost profits damages from Sarepta for any alleged infringement of the NS Patents; and

(3) the Wilton Patents are not unenforceable for inequitable conduct and there is no *Walker Process* fraud.

II. ***REPLY IN SUPPORT OF MOTION #1*: SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NOS. 9,994,851 AND 10,227,590**

NS fails to raise any genuine factual issues regarding its infringement of the Wilton Product Patents. NS's only non-infringement argument is that NS's Viltepso® (viltolarsen) does not include at least 12 consecutive bases of SEQ ID NO: 195, because Viltepso® contains thymines instead of uracils. D.I. 460 at 2-4; D.I. 466, ¶¶1.19, 1.24; *see also* D.I. 466, ¶¶1.21-1.22, 1.29-1.30.[2] But the Court's *Markman* ruling is clear: the "in which uracil bases are thymine bases" phrase modifies the "***entire antisense oligonucleotide***," including the "base sequence" limitation (at least 12 consecutive nucleotides of SEQ ID NO: 195), which ***is part of the ASO***. D.I. 248 at 28-29. Thus, NS's product infringes because it contains at least 12 consecutive nucleotides of SEQ ID NO: 195, wherein uracils are thymines. D.I. 466, ¶1.24 (Esau admission).

NS's non-infringement argument is based on an incorrect interpretation of the Court's

[2] Other than the single "base sequence" limitation NS has identified, NS does not dispute that its product meets the other claim limitations of the Wilton Product Patents. D.I. 466, ¶¶1.1-1.9, 1.11-1.16. While NS repeatedly clarifies that the active ingredient of Viltepso® (viltolarsen) is viltolarsen, NS does not dispute that Viltepso® (viltolarsen) meets the claim limitations. By failing to respond, NS therefore admits Sarepta's facts in each of these instances. *See* D.I. 143 at 11 (Scheduling Order explaining that the failure to respond to a fact shall indicate that the fact is not in dispute for purposes of summary judgment).

[redacted]

Markman ruling that results in an impossibility: claims that ***cannot cover any ASOs***. *See* D.I. 460 at 8; D.I. 466, ¶1.23. As discussed above, the plain language of the Court's *Markman* ruling precludes NS's argument. Further, the Court's characterization of the specification and prosecution history to support its construction similarly makes clear that the Court understood that the portion of the ASO corresponding to the base sequence limitation (at least 12 consecutive nucleotides of SEQ ID NO: 195)—in addition to the remainder of the ASO—is modified by the phrase "in which uracil bases are thymine bases." D.I. 248 at 28 ("[T]he Examiner understood ***that the disputed term was intended to modify the entire [ASO], not just the preceding base sequence limitation***."); *see also id*. at 27 (noting that the specification "explain[s] that thymine bases may be substituted for uracil bases when making a morpholino but [is] silent as to a combination of both uracil and thymine bases."); *id.* ("Contrary to NS's contention, the prosecution history identified by Sarepta also informs a person of ordinary skill in the art, with reasonable certainty, as to the scope of the claims. In overcoming an obviousness rejection to structurally identical claims, the applicant identified ***'uracil bases [being] thymine bases"*** as a feature of ***the claimed antisense oligonucleotide***.").

NS suggests that it is applying a claim construction that Sarepta sought during *Markman* proceedings. D.I. 460 at 1, 5-6. Not so. During *Markman*, the Court agreed with Sarepta and its expert Dr. Stein that the phrase "in which uracil bases are thymine bases" is not indefinite as NS alleged (and as NS now improperly reargues) and that it modifies the ***entire*** ASO. D.I. 248 at 25-29. The Court rejected NS's and NS's expert Dr. Hastings' position that the phrase "in which uracil bases are thymine bases" modifies ***only the portion*** of the ASO corresponding to at least 12 consecutive bases of SEQ ID NO: 195. *Id*. Sarepta never argued that the "base sequence" portion of the ASO is somehow not part of the "entire" ASO. *See* D.I. 166 at 52 (Sarepta: "The intrinsic

[redacted]

evidence establishes that thymine bases rather than uracil bases are used ***throughout the claimed antisense oligonucleotide***."). Indeed, NS's expert characterized Sarepta's position during *Markman* as "requir[ing] that no uracil bases may be used ***in the entire antisense oligonucleotide***." D.I. 171 (Ex. 43), ¶100. NS is incorrect in arguing that waiver and judicial estoppel apply. To the contrary, Sarepta's position has been consistent throughout the litigation.

In contrast, NS's position is inconsistent with its position during *Markman*. NS framed the *Markman* dispute as whether the nucleotides *outside* of the base sequence must contain thymine bases, or whether *outside* of the base sequence uracil bases are permitted. D.I. 166 at 63 (NS: "These differing constructions render uncertain whether an antisense oligonucleotide with uracil bases outside the 12 consecutive bases of SEQ ID No: 195 can infringe."); *see also* D.I. 248 at 25 (Court noting that according to NS, there are "at least two equally likely interpretations" of "in which uracil bases are thymine bases": "(1) the phrase modifies the term 'antisense oligonucleotide' ***as a whole***, such that ***no uracil bases are included anywhere in the 'antisense oligonucleotide***;'" or, (2) "the phrase modifies the sequence of bases immediately preceding it (e.g., SEQ ID NO: 195)"). Notably, NS's expert referred to Sarepta's position during *Markman* as "reasonable" and did not suggest that it would somehow render the claims nonsensical and thus indefinite. *See* D.I. 171 (Ex. 43), ¶100 ("[O]ne ***reasonable*** interpretation is that the use of the phrase "in which uracil bases are thymine bases' requires that no uracil bases may be used in the entire antisense oligonucleotide."). The Court should reject NS's attempt to re-litigate the claim construction dispute based on a theory that is precluded by the Court's *Markman* ruling and that is also inconsistent with the positions that any party (including NS) advanced during *Markman*.

NS wrongly accuses Sarepta of failing to apply the "base sequence" limitation in its infringement analysis. D.I. 460 at 2-4. Under Sarepta's analysis—consistent with the Court's

[redacted]

Markman ruling—the "in which thymine bases are uracil bases" language modifies the entire ASO—in other words, it modifies both the portion of the ASO corresponding to at least 12 consecutive bases of SEQ ID NO: 195 (i.e., the "base sequence" limitation), and also the portions of the ASO outside of the base sequence. Sarepta addresses NS's infringement of both the "base sequence" limitation and the "in which uracil bases are thymine bases" limitation pursuant to the Court's *Markman* ruling. *See* D.I. 422-1 (Ex. 18), ¶¶251-54; D.I. 427-3, ¶¶13-21. Sarepta also addresses validity of the Wilton Patents based on both of these limitations. *See, e.g.*, D.I. 427-2, ¶¶56, 66, 74, 227, 240, 319, 364, 417, 473.

Finally, NS argues that "[redacted]" D.I. 460 at 9. But in Dr. Hastings' expert report and during her deposition, Dr. Hastings [redacted] D.I. 427-5, ¶41. She also [redacted] D.I. 425-1 (Ex. 32), 157:11-158:15. Dr. Hastings does not [redacted] Moreover, the case cited by NS in support of Dr. Esau's "alternative" theory testimony, *Intel Corp. v. Future Link Sys, LLC*, related to contract issues. 268 F. Supp. 3d 605, 614 (D. Del. 2017). It does not address a situation where, as here, an expert's opinion is contrary to the Court's *Markman* ruling. *Id*. Indeed, NS fails to distinguish the cases cited by Sarepta indicating that expert testimony contrary to the Court's *Markman* ruling should be excluded. *See* D.I. 395 at 9; D.I. 457.

Because NS's noninfringement argument is based on a claim construction contrary to the Court's *Markman* ruling, Sarepta's motion should be granted. *See Cryovac Inc. v. Pechiney Plastic*

[redacted]

Packaging, Inc., 430 F. Supp. 346, 353-54 (D. Del. 2006).[3]

III. ***REPLY IN SUPPORT OF MOTION #2*: SUMMARY JUDGMENT OF NO LOST PROFITS**

NS Japan's opposition confirms that its lost profits claim is fatally infected with conjecture and guesswork. NS Japan[4] has the burden of proving, not guessing at, its lost profits damages. But it cannot eliminate the guesswork baked into its lost profits theory because its expert ***admitted*** his calculations [redacted]. D.I. 466, ¶2.16 (admitting D.I. 411, ¶2.16). NS Japan has provided ***no evidence*** that [redacted], which is fatal to its lost profits claim. [redacted] But this defective declaration actually ***worsens*** the problem. Without [redacted]. This guesswork dooms its lost profits claim.

Separately, NS Japan's assertion that it is not claiming NS Pharma's lost profits, but rather its own lost profits that [redacted] is meritless. As NS Japan admits, the [redacted]" D.I. 462

[3] For the reasons stated herein, the court should also decline NS's belated invitation to enter summary judgment of non-infringement, D.I. 460 at 10, or to find the claims invalid as indefinite, *id*. at 8. Not only is NS wrong on the law, but NS failed to make these requests in the opening round despite the opportunity to do so. NS's request for summary judgment is also precluded by the Scheduling Order that required the parties to rank order any motions for summary judgment. D.I. 143 at 12.

[4] "NS Japan" refers to Nippon Shinyaku Co. Ltd., a Japanese company and the Plaintiff in this case. *See* D.I. 324 at ¶¶5-7. "NS Pharma" refers to NS Pharma Inc., a NS Japan subsidiary incorporated in Delaware. *Id.*

[redacted]

at 2; *see also id*. at 9 (describing the [redacted]"). NS Japan's expert similarly refers to [redacted]" D.I. 425-2 (Ex. 49) at 80; *see also id.* at 81 (assessing NS Pharma's [redacted]"). Any way you slice it, NS Japan's lost profits claim is a claim to NS Pharma's lost profits.

Even assuming NS Japan could legally seek NS Pharma's lost profits, NS Japan cannot prove its share of NS Pharma's profits "flow inexorably" to it under the Agreement. There is nothing "inexorable" about amounts that [redacted] as explained above. Sarepta's motion should be granted.

A. NS Japan Cannot Prove Lost Profits

NS Japan's lost profits claim is uncertain and speculative under any label, warranting summary judgment of no lost profits. *See Promega Corp. v. Life Techs. Corp.*, 875 F.3d 651, 660 (Fed. Cir. 2017) (patentee's damages "must be proved, and not guessed at," including "proving the ***amount*** of the award") (emphasis in original) (first quoting *Philp v. Nock,* 84 U.S. (17 Wall.) 460, 462 (1873); and then quoting *Minco, Inc. v. Combustion Eng'g, Inc.*, 95 F.3d 1109, 1118 (Fed. Cir. 1996)). As NS Japan admits, [redacted]" D.I. 466, ¶2.14. The [redacted] as NS Japan also admits. *Id.* at ¶2.15; D.I. 411, ¶2.15. In other words, [redacted]

[redacted] at any time. [5] *See* D.I. 409 at 13 n.5. NS Japan's and NS Pharma's past [redacted] (*see* D.I. 462 at 8-14) because NS Japan has not proven that the [redacted], which is required to determine the royalty amount with certainty. Without approval of [redacted] (D.I. 466 ¶2.17; D.I. 411 ¶2.17)), [redacted] *See* D.I. 409 at 10-11.

Far from a "red herring" (D.I. 462 at 11), this point is central to and dispositive of NS Japan's lost profits claim. Without the [redacted], there is nothing certain about [redacted]. NS Japan's case rests purely on conjecture about what two different governments might or might not accept. This uncertainty is sufficient to grant summary judgment of no lost profits because NS Japan cannot "le[ave] [damages] to conjecture by the jury." *Promega Corp.*, 875 F.3d at 660.

NS Japan recognizes this problem in its opposition, but only makes it worse. Specifically, it includes a new, four-sentence declaration from an NS Pharma employee, Gardner Gendron. D.I. 468-22. Setting aside multiple evidentiary problems with this declaration,[6] Mr. Gendron does

[5] As NS Japan admits, as of the service of expert reports in this case, NS Pharma had not [redacted] D.I. 466, ¶2.12. Thus, there has been no [redacted] to challenge yet.

[6] At the outset, to the extent that the declaration purports to suggest [redacted] it is inadmissible (perhaps double) hearsay. FED. R. EVID. 801. Moreover, Mr. Gendron [redacted] *See generally* D.I. 468-22. [redacted] *Id.* at ¶3. Mr. Gendron's declaration is thus deficient at least under FED. R. CIV. P. 56(c)(4), which requires that a "declaration used to support or oppose a [summary judgment] motion must be made on personal

[redacted]

not try to address [redacted]. Even if Mr. Gendron's declaration may be considered, [redacted] *Id.* at ¶2. Mr. Gendron also [redacted] *Id.* at ¶3. He does not give ***any*** basis for this "[redacted] In short, Mr. Gendron's declaration is just rank speculation—[redacted] At best, it confirms that there is [redacted] (which NS Japan separately admitted, D.I. 466, ¶2.17).

By remaining silent on [redacted] NS Japan has all but admitted that [redacted] remains uncertain and in flux. Its theory of how much it would [redacted] is therefore based entirely on guesswork and speculation, which cannot be presented to the jury.

B. NS Japan Improperly Seeks NS Pharma's Lost Profits and Cannot Show Those Profits Flow Inexorably to It

NS Japan spends over four pages arguing that, despite its own and its expert's admissions, it does not seek recovery of NS Pharma's lost profits but instead seeks a new form of damages it

knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Further, "conclusory, self-serving affidavits are insufficient to withstand a motion for summary judgment." *Jackson v. Se. Pa. Transp. Auth.*, No. 21-2671, 2023 WL 195156, at *3 (3d Cir. Jan. 17, 2023) (quoting *Kirleis v. Dickie, McCamey & Chilcote, P.C.*, 560 F.3d 156, 161 (3d Cir. 2009)).

[redacted]

suffered as a supplier to NS Pharma (*see* D.I. 462 at 3-4 (arguing "'lost profits' is not the exclusive damages theory available")) that is somehow also "a classic measurement of lost profits" (*id.* at 7). First, any new theory of damages cannot defeat summary judgment because NS Japan did not disclose it during fact or expert discovery. *See NexStep, Inc. v. Comcast Cable Commc'ns, LLC*, C.A. No. 19-1301-RGA, 2021 WL 5356293, at *2 (D. Del. Nov. 17, 2021) (striking new damages theory introduced after discovery closed). Second, NS Japan's whiplash-inducing argument is nonsense. In reality, NS Japan asserts that [redacted]. This is precisely what NS Japan's damages expert did to reach his lost profits opinion. D.I. 425-2 (Ex. 49) at 81 ([redacted] "[redacted] and opining "[redacted]").

Related companies "may not enjoy the advantages of their separate corporate structure and, at the same time, avoid the consequential limitations of that structure." *Poly-Am., L.P. v. GSE Lining Tech., Inc.,* 383 F.3d 1303, 1311 (Fed. Cir. 2004). [redacted] As Judge Noreika explained, "[a]lthough this distinction may appear overly formalistic, the Federal Circuit has explained that two companies that benefit from dividing patent ownership from sale of the patented product must also accept the consequence that the patent owner will be unable to claim the lost profits experienced by the seller." *Intuitive Surgical, Inc. v. Auris Health, Inc.*, No. 18-1359-MN, 2021 WL 3662842, at *3 (D. Del. Aug. 18, 2021); *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548 (Fed. Cir. 1995) ("Normally, if the patentee is

[redacted]

not selling a product, by definition there can be no lost profits."). As in *Intuitive*, NS Japan [redacted]

The only case NS Japan cites as allegedly endorsing its lost profits theory spent only three paragraphs discussing lost profits. D.I. 462 at 5 (citing *In re Biogen '755 Patent Litig.*, C.A. No. 10-2734-CCC-JBC, 2018 WL 3586271, at *19 (D.N.J. July 26, 2018)). That court did not analyze the issue in depth, stating rather that "[o]n the present record, and upon review of the cited cases" it would allow the patentee to present its damages theory at trial where it (unlike NS Japan) had also produced evidence of inexorable profit flow.[7] Judge Noreika in *Intuitive* expressly distinguished the *Biogen* situation from the one in which NS finds itself. Where, as here, the patentee "has only provided a theory of [a related company's] lost profits and a conclusory statement that the profits of [the related company] inexorably flow to [the patentee][,] . . . the patent owner will be unable to claim the lost profits experienced by the seller." *Intuitive*, 2021 WL 3662842, at *3 & n.5. As in *Intuitive*, NS Japan (through its damages expert Mr. Hosfield) provides a theory of NS Pharma's lost profits [redacted], then offers the conclusory statement that "[redacted] D.I. 425-2 (Ex. 49) at 60; *id.* (Ex. 50), 112:15-22. Further, Mr. Hosfield's supposition is wrong, as detailed in Sarepta's motion (D.I. 409 at 9-13) and above, and as NS Japan essentially admits in its opposition and new declaration.

[7] The jury found Biogen's patent claims invalid as anticipated, so it never reached the question of lost profits. *In re Biogen '755 Patent Litig.*, C.A. No. 10-2734-CCC-JBC, D.I. 977, Verdict at 4-5 (D.N.J. Feb. 23, 2018).

[redacted]

C. Conclusion

Sarepta's motion should be granted.

IV. ***REPLY IN SUPPORT OF MOTION #3*: SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT AND NO *WALKER PROCESS* FRAUD**

A. Summary of Argument

Dr. Wilton and Dr. Fletcher are highly respected scientists who have dedicated their lives to finding treatments for DMD—a devastating and fatal disease. *See* Ex. 8, 1; Ex. 2, 189:22-191:14. In the Wilton Patents, they identified, for the first time, a discrete region within human exon 53 amenable to exon skipping (i.e., a hot spot), which led to the ***first ever*** approved drug for patients amenable to treatment by exon 53 skipping. D.I. 469, 3-4. Their achievements have received widespread praise in the scientific and patient communities—and were relied on by NS in its follow-on exon skipping studies. *Id.*; D.I. 427-1, ¶¶141, 147.

NS's inequitable conduct and *Walker Process* fraud allegations attack those achievements, contending without evidence that the inventors and others associated with the Wilton Patents had a specific intent to deceive the PTO, and that those patents were fraudulently obtained. But NS's opposition brief confirms that summary judgment of no inequitable conduct and no *Walker Process* fraud is warranted. It is undisputed that NS, through its expert Dr. Kamholz, applied an incorrect "knew or should have known" standard to assess intent, which was expressly rejected by the *en banc* Federal Circuit. *Therasense v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290-91 (Fed. Cir. 2011) (en banc). This alone warrants summary judgment.

Further, NS failed to identify any evidence of specific intent under the controlling legal standard, i.e., that the inventors or anyone involved in prosecuting the Wilton Patents: (1) ***knew*** they were making a misrepresentation to the PTO at the time they made it with the ***specific intent to deceive*** the PTO; or (2) ***knew*** of allegedly withheld information, ***knew*** it was material, and made

[redacted]

a ***deliberate*** decision to withhold it. While NS resorts to conjecture, NS adduced no evidence of deceptive intent. NS's theory is exactly the type of inequitable conduct claim that "plagued not only the courts but also the entire patent system." *Id.* at 1289-90. Summary judgment is warranted.

B. NS's Opposition Confirms that Summary Judgment Is Warranted

1. NS Cannot Walk Away from the Incorrect Legal Standard of Intent That It and Its Expert, Dr. Kamholz, Applied

NS does not dispute that the "knew or should have known" standard for evaluating intent was rejected by the *en banc* Federal Circuit in *Therasense*. *See generally* D.I. 464. NS also does not dispute that Dr. Kamholz applied this incorrect standard in rendering his inequitable conduct opinion. *See* D.I. 466, ¶¶3.17, 3.18, 3.20 (admitting that Dr. Kamholz opined that the involved individuals "knew or should have known" allegedly "false or misleading" information).

NS's sole response is to dismiss Dr. Kamholz's opinion altogether, contending that he "has not offered opinions on intent." D.I. 464 at 10. Not so. The ***only*** reason Dr. Kamholz opined on what various individuals allegedly "knew or should have known" was to provide his views on intent—what individuals "knew or should have known" has nothing to do with materiality, which evaluates whether the PTO would have allowed the claims but for the allegedly withheld or misrepresented information. *Therasense,* 649 F.3d at 1291. Further, NS's dismissal of his opinion here conflicts with its position taken in response to Sarepta's *Daubert* motion. There, NS contends that Dr. Kamholz applied the "knew or should have known" standard so that the Court can "decide" whether the individuals involved "knew of the false or misleading statements" (i.e., specific intent) and "in fact committed inequitable conduct under the *Therasense* standard." *See* D.I. 456, 3-4. Because NS concedes that its inequitable conduct claim is based on an incorrect legal standard, summary judgment is warranted as a matter of law. D.I. 409 at 19-20 (collecting cases).

[redacted]

2. NS Fails to Proffer Evidence that Deceptive Intent Was the Single Most Reasonable Inference

NS also cannot prevail on its inequitable conduct claim because NS has proffered ***no evidence*** of a specific intent to deceive the PTO**.** *See* D.I. 464 at 2-5. Instead, NS speculates that in its view, the inventors "must have been aware of," "would necessarily have had to review," and "would have seen" certain information because "purported negligence or oversight" is "highly improbable." *See id.* This is no more than NS's subjective and unsupported belief that the inventors ***should have known*** of certain information, which the Federal Circuit held "does not satisfy [the] intent requirement." *See Therasense*, 649 F.3d at 1290. Regarding the prosecuting attorney it accused of inequitable conduct, Ms. Mandragouras, NS is entirely silent. *See* D.I. 464 at 3-5.

In brand-new allegations, NS suggests that a specific intent to deceive the PTO can be inferred from certain "post-prosecution" activities: (1) Sarepta's assertion of the Wilton Patents, [redacted]; and (2) [redacted] *Id*. at 4-5. But "an inference based upon a speculation or conjecture does not create a material factual dispute sufficient to defeat entry of summary judgment." *Halsey v. Pfeiffer*, 750 F.3d 273, 287 (3d Cir. 2014) (citation omitted).

Further, such allegations are nowhere to be found in NS's inequitable conduct pleadings (D.I. 324), where NS was required to state its allegations with particularity. FED. R. CIV. P. 9(b). As the Third Circuit explained, the heightened Rule 9 pleading requirement safeguards defendants from "spurious charges of immoral and fraudulent behavior." *See Hawk Mountain LLC v. Mirra*, No. 13-2083-SLR-SRF, 2016 WL 4541032, at *2 (D. Del. Aug. 31, 2016) (quoting *Grant v. Turner*, 505 F. App'x 107, 111 (3d Cir. 2012)). Regardless, enforcement of the Wilton Patents ***did not involve*** the inventors and prosecuting attorneys accused of inequitable conduct. And the patents issued months before Sarepta secured approval of its exon 53 skipping drug. *See* D.I. 417-

[redacted]

2 (Ex. 3), item (45) ("Apr. 23, 2019"); Ex. 11 (FDA announcement of the approval dated December 2019). These allegations are irrelevant to an inference of intent, which must involve "deceiving the PTO." *Therasense*, 649 F.3d at 1290.

The cases cited by NS do not state otherwise. In *Regeneron Pharms., Inc. v. Merus N.V.*, the patentee was accused of "engaging in inequitable conduct *during* prosecution." 864 F.3d 1343, 1364 (Fed. Cir. 2017) (emphasis in original). An adverse inference of intent to deceive the PTO was drawn from "widespread litigation misconduct," which "obfuscated its prosecution misconduct." *Id.* No such allegation has been made here. To the contrary, despite extensive discovery, NS has uncovered no evidence of deceptive intent. *Keystone Driller Co. v. General Excavator Co.* does not involve inequitable conduct, and moreover involved bribing an affiant to conceal invalidity issues. 290 U.S. 240, 243 (1933). Again, no such conduct is alleged here.

NS's inequitable conduct arguments seek to baselessly sully reputable scientists—wrongly accusing them of [redacted] and a [redacted] (D.I. 464 at 3, 9)—without any evidence of intent. This failure of proof independently warrants granting summary judgment here. *See Therasense*, 649 F.3d at 1290 (tightening the standard for intent, as inequitable conduct "has been overused to the detriment of the public").

3. NS's Attempt to Create Genuine Disputes of Material Fact Also Fails

NS contends that "disputed factual issues preclude summary judgment." D.I. 464 at 5-10. But NS acknowledges the "disputed facts" [redacted] concern materiality, not intent. *See id.* at 5-6. Each of the additional "disputed facts" identified by NS similarly relates to materiality, not intent. *See id.* at 6-10. Because the basis for Sarepta's motion is NS's failure of proof with respect to the ***intent*** prong, these facts cannot prevent summary judgment. D.I. 409 at 15 n.7. Despite having no bearing on Sarepta's motion, Sarepta nevertheless addresses them below to clarify the record.

[redacted]

[redacted]: According to NS, [redacted] s": (1) [redacted]; and (2) [redacted][8] D.I. 464 at 2-3. Based on this, NS argues [redacted] *Id*. at 6-7. Both the premise and conclusion are incorrect.

This [redacted] has nothing to do with a specific intent to deceive the PTO. It also is not material. There is no dispute that an ASO designed to target nucleotides 23 to 47 of human exon 53 induces exon skipping. *See* D.I. 465, ¶¶13, 18; D.I. 427-2, ¶¶157, 161, 198. There is also no dispute that the claims of the Wilton Patents do not require skipping at any particular concentration. D.I. 471-1 (Ex. 4), 127:13-128:6; D.I. 427-2, ¶117. [redacted] there is no dispute that H53A(+23+47) induces exon skipping, as reported in the Wilton Patents. *See* D.I. 427-2, ¶¶151-157; D.I. 417-1 (Ex. 1), Table 39.

Because the [redacted] Given its immateriality, it is unsurprising that Dr. Wilton had no recollection of it.[9] D.I. 411, ¶3.22.

Harding 2007: NS argues—without any evidentiary support whatsoever—that Drs. Wilton

[8] NS wrongly states that the Wilton Patents reports exon skipping "***at*** 50 nM," when they in fact report skipping "to 50 nM." D.I. 464 at 3. This description ("very faint exon skipping to 50 nM") is consistent with [redacted] D.I. 427-2, ¶¶152-153.

[9] Contrary to NS's assertion that the Court "must assess" witness credibility (D.I. 464 at 8-9), courts routinely grant summary judgment of no inequitable conduct where, as here, the record does not support a reasonable finding of a deceptive intent. *See* D.I. 409 at 23-24 (collecting cases).

[redacted]

and Fletcher [redacted] in attesting that they believe they are the inventors of the Wilton Patents because their later publication, Harding 2007, allegedly "refutes" that they: (1) identified a discrete region spanning nucleotides 23 to 69 of human exon 53 amenable to exon skipping (i.e., the hot spot); and (2) invented a genus of ASOs targeting the region defined by, *inter alia*, having "at least 12 consecutive bases" of SEQ ID NO: 195.[10] D.I. 464 at 7-9.

The facts relating to Harding 2007 are wholly inconsistent with an intent to deceive. Indeed, ***Harding 2007 was repeatedly submitted to the PTO*** during prosecution of the Wilton Patents and repeatedly considered by the examiner, negating any inference of a specific intent to deceive the PTO. *See* D.I. 466, ¶¶3.6-3.7, 3.13-3.16; Ex. 13, SRPT-VYDS-0091381 (Hardin 2007 submitted), -662 (Harding 2007 considered); Ex. 14, SRPT-VYDS-0124360 (Harding 2007 submitted), -9048 (Harding 2007 considered); Ex. 15, SRPT-VYDS-142641 (Harding 2007 submitted), -150608 (Harding 2007 considered). NS's conjecture that its submission to the PTO was done "to obscure its significance" (D.I. 464 at 9-10) finds no support in the record, and NS cites none. Certainly, it does not constitute evidence that "a factfinder could reasonably find that deceptive intent was the single most reasonable inference," as required at summary judgment. *Sysmex Corp. v. Beckman Coulter, Inc.*, C.A. No. 19-1642-JFB-CJB, 2022 WL 1503987, at *4 (D. Del. May 6, 2022), *report and recommendation adopted*, 2022 WL 1744573 (D. Del. May 31, 2022).

NS's argument is also factually incorrect and immaterial. NS conflates identification of the hot spot, reported in the Wilton Patents, with later optimization efforts involving ASOs targeting that hot spot. As Dr. Wilton explained, Harding 2007 does not repudiate the hot spot, but instead reflects "further refinement." D.I. 468-1, 111:4-13. Similarly, NS's contention that the inventors

[10] NS omits other structural features that define the claimed ASOs. *See* D.I. 469 at 7-9.

[redacted]

did not invent a genus of ASOs having "at least 12 consecutive bases" of SEQ ID NO: 195 is based solely on NS's mischaracterization of deposition testimony. *See* D.I. 464 at 8. Dr. Wilton testified [redacted] *See* D.I. 468-1, 228:10-18, 229:18-230:5. Dr. Fletcher explained that [redacted] *See* Ex. 2, 161:6-19.

In sum, NS's "disputed" facts regarding Harding 2007 are irrelevant to intent; lack evidentiary support; and fail to raise any genuine dispute precluding summary judgment.

Ms. Mandragouras' Alleged Obligation to Investigate: NS disputes whether Ms. Mandragouras should have re-investigated the inventorship and [redacted] of the Wilton Patents in view of Harding 2007. D.I. 464 at 10. This too is irrelevant to a specific intent to deceive the PTO, for which NS has cited no support. *See also* Ex. 3, 22:22-23:3 (Ms. Mandragouras testifying that she believed "inventorship had been established before [she] assumed responsibility"). Further, as discussed above, given that the Harding 2007 paper is not material to patentability, there was no need for re-investigation.

C. Conclusion

NS acknowledges that "its *Walker Process* fraud antitrust claim rises and falls with its inequitable conduct claim." D.I. 464 at 11. Because NS both failed to apply the correct legal standard *and* proffer evidence such that a factfinder could reasonably conclude that deceptive intent was the ***single most reasonable inference***, NS has necessarily failed with respect to its inequitable conduct and *Walker Process* fraud claims. Summary judgment as to both is warranted.

[redacted]

V. CONCLUSION

For the forgoing reasons, Sarepta and UWA respectfully request that the Court grant summary judgment based on the three separate grounds briefed herein and in their opening brief (D.I. 409), as specified in the previously filed motions (D.I. 396-398).

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January 26, 2024

CERTIFICATE OF SERVICE

I hereby certify that on January 26, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 26, 2024, upon the following in the manner indicated:

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